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ACOUSTICALLY BASED FETAL HEART RATE MONITOR

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ABSTRACT

The acoustically based fetal heart rate monitor permits an expectant mother to perform the fetal Non-Stress Test in her home. The potential market would include the one million U.S. pregnancies per year requiring this type of prenatal surveillance. The monitor uses PVF2 piezoelectric polymer film for the acoustic sensors, which are mounted in a seven-element array on a cummerbund. Evaluation of the sensor output signals utilizes a digital signal processor, which performs a linear prediction routine in real time. Clinical tests reveal that the acoustically based monitor provides Non-Stress Test records which are comparable to those obtained with a commercial ultrasonic transducer.

INTRODUCTION

It has been known for a long time that fetal heart rate (FHR) patterns reflect fetal well-being. If a fetus's oxygenation status deteriorates (early asphyxiation), its heart rate will compensatorily increase. This is not surprising because adult hearts respond similarly when adults get short of breath (a form of asphyxiation) with exercise. Later, with continued hypoxic stress, the FHR slows due to metabolic stagnation and creates a true threat to fetal well-being termed *fetal distress*. The FHR, therefore, would be expected to accelerate with in-utero fetal movement. This is what happens in the healthy fetus while the absence of FHR accelerations suggests that the fetus may be in jeopardy. This knowledge has sponsored the impetus for generating our current hospital-based FHR monitoring equipment and establishing FHR reference standards. The best known test of fetal well-being is the Non-Stress Test (NST), which relies on FHR changes in relationship to fetal movement.

PORTABILIZING THE NON-STRESS TEST

Each NST costs anywhere from \$125-250, entails hospital paperwork, inconvenience and fragmentation of care for the patient, and requires the attendance of nursing personnel who are presently in short supply. All of this technology could be converted to a portable computer-based, automated form utilizing a plurality of passive surface pressure sensors capable of performing the same testing. Such an approach would not involve the intentional creation and injection of an energy source into the pregnant woman and her fetus as occurs with ultrasound. Such automation would be more economical, thus improving the potential for increased fetal surveillance while easing the burden on strained nursing resources. Further, automation would be more scientific than its error-prone subjective strip chart interpretation counterpart. Its portability feature could overcome certain patient limitations (rural areas, patient paralysis, complete lack of transportation...) and in some areas the cultural paranoia of the "white coat" community by making itself available in the home or a local satellite facility. Further, by increasing prenatal surveillance, tragic outcomes such as cerebral palsy could be prevented one day.

The initial market would target the obstetrician's office and his high-risk Ob population. He would employ it and would receive direct payment instead of the hospital. The revenue derived would enable him to purchase the monitor rather quickly while appealing to his patients' sense of economy and convenience. Ultimately the patient would apply the passive sensor array/abdominal cummerbund unit to herself at home.

Either data transmission via phone link or an on-site automatic readout would be available in that case. In all circumstances, the commonly accepted NST would be performed.

The NST is routinely covered by insurance companies and public assistance facilities. Since one million of our three million annual pregnancies require periodic NST evaluations, realistic commercialization forecasts have predicted a \$100 million per year industry potential in the U.S. alone for portable fetal monitoring. This prediction does not include the potential service revenue to distributors nor its tangible or intangible preventative health care value to society in general.

The previously mentioned automatic nature of the unit would lend itself to patient or para-professional application. In part, the automatic feature relies on a plurality of lightweight surface pressure sensors attached to an attractive cummerbund which the mother places on her abdomen. This is needed because the characteristic fetal heart sound is a localized, yet randomly placed acoustic event. The fetal heart sound is heard only in proximity to where the fetal back is in contact with the maternal abdomen--a roughly circular area having a diameter of about 3 cm. Since the fetus moves with some frequency, a plurality of transducers is required to anticipate all locations of this expected sound. Coupled to this plurality is a computer programmed to scan over the transducers with fetal heart sound and rate recognition capabilities. Either the mother or an accelerometer activation would signify when fetal movement occurred. Once tracking the FHR/movement events, the computer would automatically compare the tested fetal NST to acceptable norms, the outcome of which would be relayed to the physician via automatic strip chart or data phone link. Such NST could be performed at \$25/test--a 10-fold saving over our current expenses.

TECHNICAL DESCRIPTION OF THE MONITOR

A block diagram of the monitor hardware is shown in Fig. 1. It consists of two components: a pressure sensor array mounted on a belt worn by the mother and an electronic support system.

The final version of the belt evolved over three generations of development, each an improvement over its predecessor. Only the second and third generation belts, shown in Figs. 2 and 3, were used in clinical studies. The second generation belt, containing three sensors in a linear arrangement, was compact enough to be used simultaneously with a commercial ultrasonic monitor. The third generation belt, containing a seven element sensor array to cover the 12-cm diameter range of the fetal heart tone, represents a final practical embodiment.

The electronic support system comprises instrumentation amplifiers to amplify the signals from the sensors; a multiplexer to permit the choice of the best located sensor; a bandpass filter (20-55 Hz); a digital signal processor to implement a linear prediction routine and to yield the FHR in real time; a parallel A/D converter to display the tone on a video display; and a strip chart recorder to indicate the FHR and fetal movement. This system is not yet portabilized and was developed specifically to test the monitor concept. Some of the components serve only to expedite a comparison of the ultrasonic and acoustic NSTs and would not be included in the final version of the portable monitor. Details are given in ref. 1.

Each sensor on the belt is designed to fulfill five functions: signal detection, acceleration cancellation, acoustical isolation, electrical shielding, and electrical isolation of the mother. A cross section and cutaway views of the sensors installed on the second generation belt are shown in Fig. 4. The construction is similar on the third generation belt, except that the electrical conduits are etched on a flexible printed circuit foil.

The internal sensor detects pressure pulses on the maternal abdomen. As recommended by the manufacturer (ref. 2), two PVF2 piezoelectric polymer elements are arranged in a bimorph structure. Here the bimorph operates in the compressional mode with e_{33} the active piezoelectric modulus. Electrical contacts to the Ni electrodes are made with conducting epoxy. The external sensor, identical in construction, is intended to cancel accelerations due to rigid body motion of the mother. A layer of kevlar wool serves to

attenuate signals due to ambient noise. The two sensors are connected differentially to the instrumentation amplifier. The Ni plate attached to the belt is bonded to both bimorphs and assures that both are subjected to the same accelerations. A foil of Cu coated kapton completely surrounds the sensor assembly. When the ground wire connected to the Cu coating contacts earth ground, the ubiquitous 60 Hz interference plummets into the background. A final layer of RTV silicone rubber, completely covering the Cu shield, isolates the mother from earth ground but is acoustically transparent. The belt itself is made of nylon parachute webbing. It does not have to be drawn tightly around the mother, rather requiring only minimal acoustic contact, but must have a sufficiently high modulus to resist displacement by the incident pressure pulses and thus assure adequate compression of the PVF2 foil.

CLINICAL VALIDATION OF THE PORTABLE MONITOR

The fetal non-stress test (NST) is performed routinely in hospitals by means of pulsed Doppler ultrasound. A normal NST requires three separate FHR accelerations of at least 15 beats per minute over its baseline. Each acceleration event is to be stimulated by an associated fetal movement. These three acceleration/movement events are to occur during any 20-minute observation window. When the mother perceives a fetal movement she records this event by pressing a push-button switch. The fetal heart rate measured by the sensor is recorded continuously on a strip chart recorder. The tests described here were conducted on patients who came to the Eastern Virginia School of Medicine, Norfolk, Virginia, for regular appointments, and then volunteered to take a subsequent test with the acoustically based monitor.

Figure 5 shows a FHR recorded simultaneously by an ultrasonic transducer and a sensor on the second generation belt, which were mounted together on the patient. The arrows at the bottom of the strip chart indicate fetal movement (FM). The acceleration in the FHR of about 15 beats per minute following the fetal movements indicate that this is a normal NST. There is good correlation between the ultrasonic and acoustic recordings.

Figure 6 shows a FHR recorded by means of the third generation belt alone. The width of the belt precluded simultaneous mounting with an ultrasonic transducer. A fetal movement is indicated by a spike right on the recording. The FHR acceleration following the FM confirms that the acoustically based monitor is capable of performing the NST reliably.

The acoustically based fetal heart rate monitor offers the advantages of portability, low cost, increased frequency of surveillance, and home-use by the patient with minimal instruction. Finally, the monitor is truly non-invasive since it does not inject energy flux into the developing fetus.

REFERENCES

1. R. A. Pretlow, "Signal Processing Methodologies for an Acoustic Fetal Heart Rate Monitor," M.S. Thesis, Old Dominion University, April, 1991.
2. *Kynar Piezo Film Technical Manual*, Pennwalt Corp., Valley Forge, PA 19482, 1987.

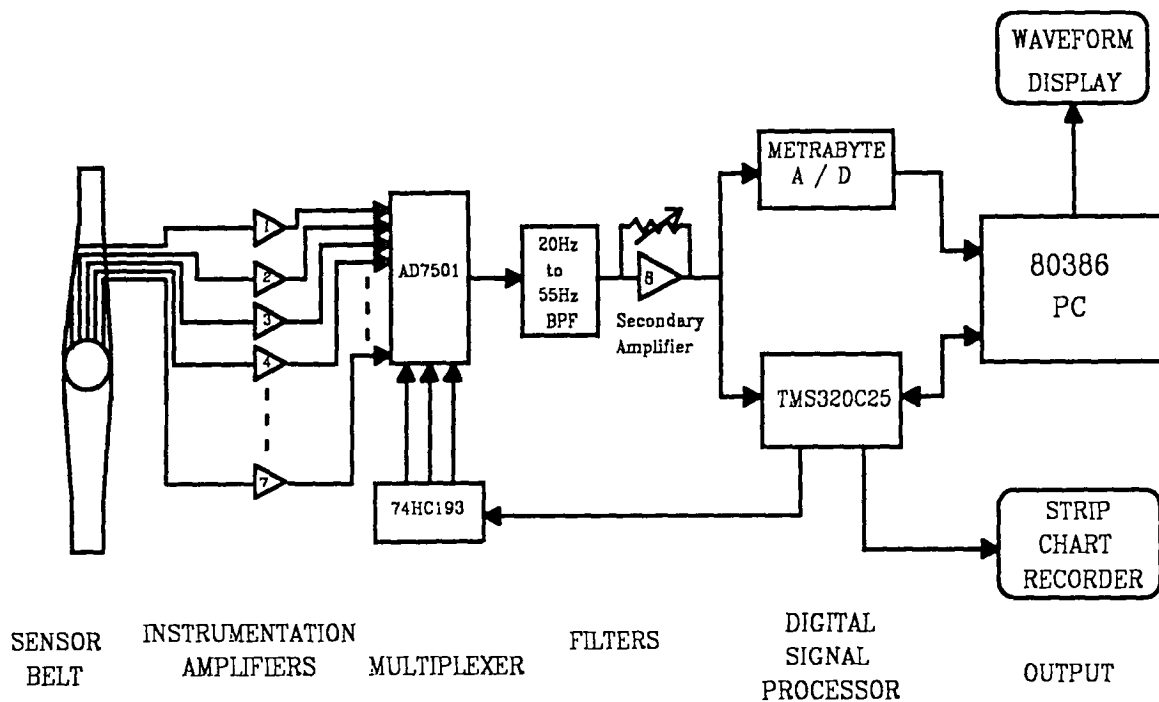


Figure 1. Block diagram of the monitor hardware.

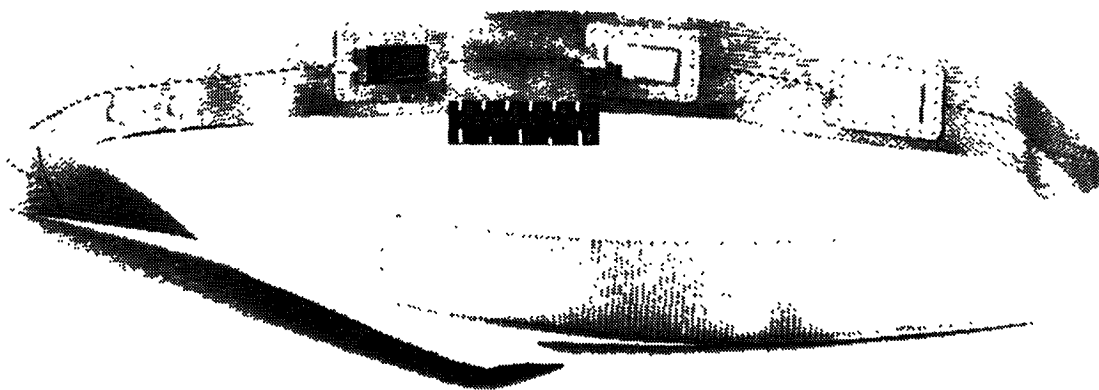


Figure 2. The second generation belt prior to installation of the shielding electrodes.

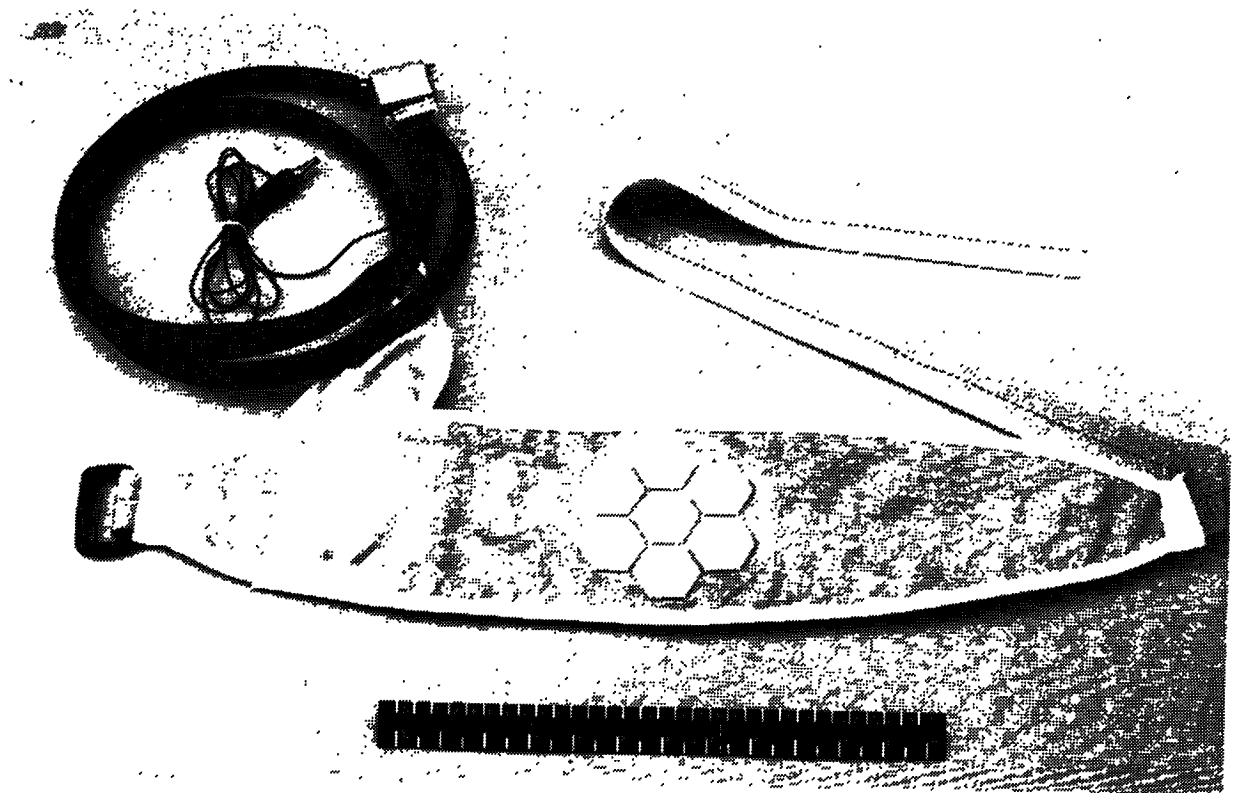


Figure 3. The third generation belt.

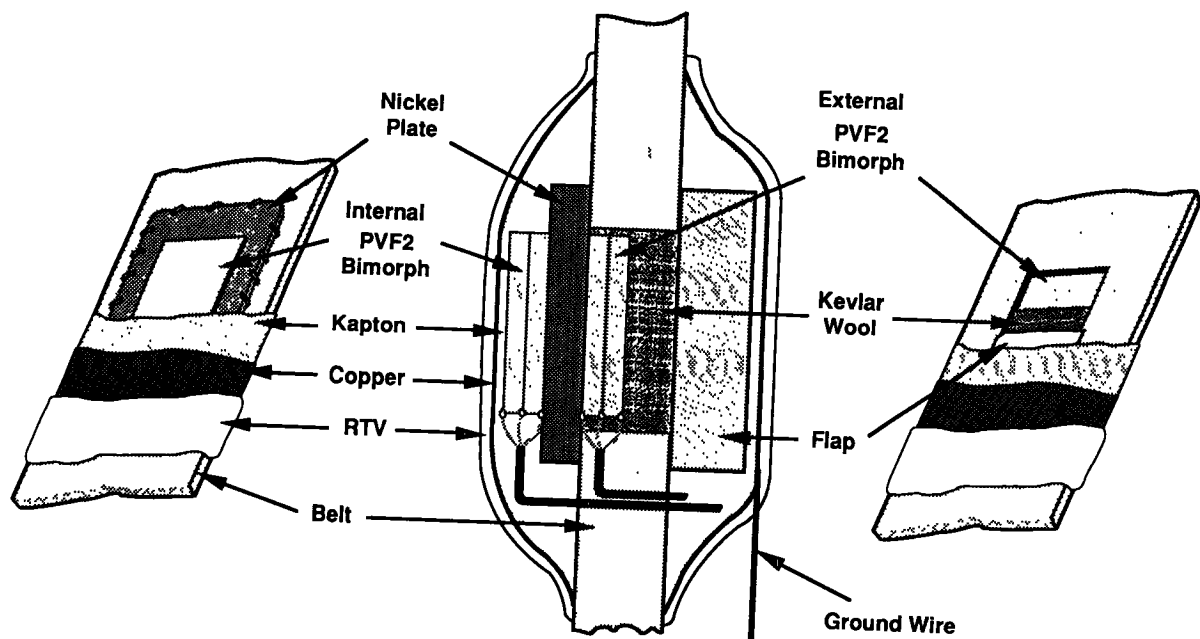
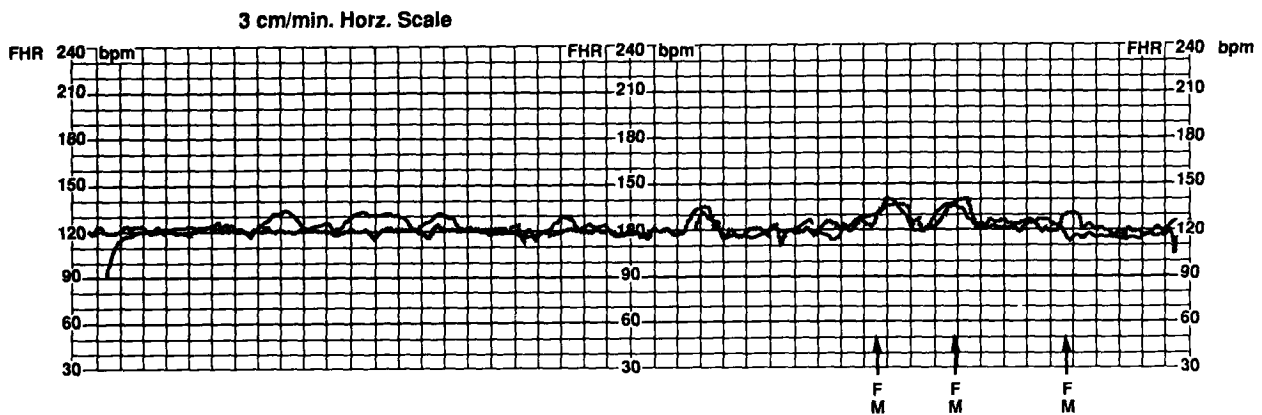


Figure 4. A cross section and cutaway views of the second generation belt.

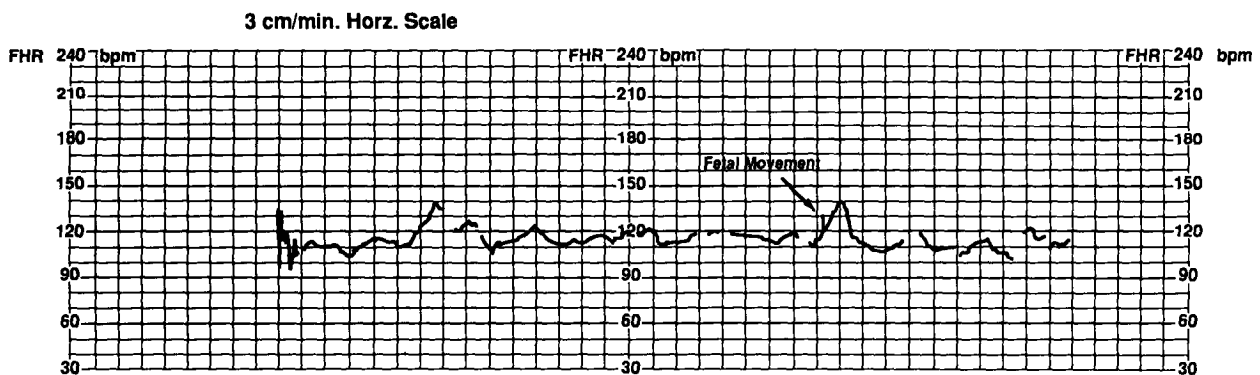


PATIENT 23

ULTRASONIC

ACOUSTICAL ———

Figure 5. A fetal Non-Stress Test recording: comparison between ultrasound and the acoustic monitor.



PATIENT 31

Figure 6. A Non-Stress Test recording acquired from the third generation belt.